SCIENTIFIC PAPER

Transabdominal Preperitoneal Herniorrhaphy using Laser-Assisted Tissue Soldering in a Porcine Model

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ABSTRACT

Background and Objectives: Collagen solder is capable of fixation of surgical meshes during laparoscopic herniorrhaphy without compromising tissue integration, increasing adhesions or inflammation. This pilot study describes development of instrumentation and techniques for transabdominal preperitoneal (TAPP) herniorrhaphy using laser-assisted soldering technology.

Methods: Anesthetized 20-kg to 25-kg female Yorkshire pigs underwent laparoscopy performed using a 3-trocar technique. Peritoneal incisions were made and pockets created in the preperitoneal space for mesh placement. Parietex TEC mesh segments embedded in 60% collagen-solder were soldered to the muscle surface by using a prototype laser (1.45μ, 4.5W CW, 5mm spot, and 55°C set temperature) and custom laparoscopic handpiece. Parietex TEC mesh segments (Control) were affixed to the muscle with fibrin sealant (Tisseel). Peritoneal closure was with staples (Control) or by soldering collagen embedded Vicryl mesh segments over the peritoneal incision (Mesh/TAPP). Segments were inserted using a specially designed introducer. Animals were recovered and underwent second-look laparoscopy at 6 weeks postimplantation. Mesh sites were harvested after animals were euthanized.

Results: The mesh-solder constructs were easily inserted and affixed in the TAPP approach. Tisseel tended to drip during application, particularly in vertical and ventral locations. Postoperative healing was similar to Control segments in all cases. Mesh/TAPP closures healed without scarring or adhesion formation.

Discussion and Conclusion: Collagen-based tissue soldering permits normal wound healing and may mitigate or reduce use of staples for laparoscopic mesh fixation and peritoneal closure. Laser-assisted mesh fixation and peritoneal closure is a promising alternative for laparoscopic herniorrhaphy. Further development of this strategy is warranted.

Key Words: Mesh fixation, Laparoscopic herniorrhaphy, Laser surgery, Collagen, Tissue solder, Hernia, Fibrin glue, Fibrin sealant.

INTRODUCTION

Herniorrhaphy is a common surgical procedure, with a variety of open and laparoscopic techniques being used successfully. Both open surgical and laparoscopic techniques require the dissection and delineation of the boundaries of the defects, the placement of a suitable prosthesis, and its fixation to the abdominal wall or the peritoneal surface.[1–8] Laparoscopic inguinal herniorrhaphy using the transabdominal preperitoneal technique (TAPP) also requires the development and closure of peritoneal flaps.

Studies describing the use of surgical glues to augment or replace conventional methods for mesh fixation have been reported.[8–11] Fibrin glue use has resulted in initial tensile strengths that were as strong as staples, but evidence of strong fibrous reaction and intense inflammatory response have been observed.[9,10] Similar results have been observed with cyanoacrylate.[8,10]

Numerous studies[11–17] have reported the efficacy of light-activated solders to weld soft tissues. Laser activation provides additional benefits, including a directed energy source for precise placement of the weld and is a method that is compatible with minimally invasive surgical techniques, with minimal damage to adjacent tissues.[16,17] Previous work from our laboratory demonstrated that laser-assisted collagen solder is capable of fixation of surgical meshes without interfering with tissue integration, increasing adhesions, or increasing inflammation intraperitoneally in animal models of intraperitoneal onlay mesh repair (IPOM).[18–20]

The present pilot study was undertaken to investigate the

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feasibility of using derivatized collagen solder for mesh fixation and peritoneal closure for laparoscopic transabdominal preperitoneal herniorrhaphy (TAPP).

MATERIALS AND METHODS

Solder Preparation

Preparation of collagen solder films has been described previously.[18–20] Briefly, purified, telopeptide-poor Type I collagen is derivatized with glutaric anhydride. The degree of derivatization is selected so that the modified collagen remains soluble at physiologic pH. Derivatization is performed by adjusting the pH of soluble collagen (5 mg/mL) to 9.0, using NaOH, adding solid anhydride to the collagen in the range of 10% to 30% (w/w) solution and maintaining the pH at 9.0 during the reaction. After 15 minutes, the pH of the solution is reduced to about 4.5 to precipitate derivatized collagen. The precipitate is recovered by centrifugation at 14500 RPM for 20 minutes and at 9°C. The precipitate is washed twice with sterile water. The final precipitate is dissolved in 5 mM phosphate buffer at pH 7.2 at a final concentration of 5mg/mL. The solution is freeze-dried in trays at a controlled rate. Solder films are prepared from the lyophilized stock collagen. Lyophilized sheets are cut into small pieces and homogenized in a tissue mill (IKA A11; IKA Works, Inc, Wilmington, NC). Films are prepared by dissolving collagen powder in distilled, sterile water. Collagen solid concentrations range from 30% to 50% and are obtained by exposing the dispersions to a controlled temperature water bath. As the collagen dissolves, more is added until the desired weight to volume concentration is achieved. The viscous solution is centrifuged with mesh segments and poured into molds. To control film thickness, a Teflon plate is pressed onto the filled mold while the mixture is still warm. Parietex TEC (Covidien, Inc, Mansfield, MA) flat-weave polyester mesh and Vicryl (Ethicon, Inc., Somerville, NJ) polyglactin mesh segments (5 cm x 5 cm) are embedded in 60% collagen solder. The mesh-solder constructs are removed from the mold after cooling for 3 minutes, vacuum packaged, labeled, and stored at 4°C until sterilization. The prepared packaged mesh solder films are subsequently sterilized by E-beam prior to their use.

CEE Laser System and Delivery Devices

The laser system contains a fiber laser, controller board for the sensor, switches, displays, indicator lamps, interfaces, calibration hardware, and an ambient air-cooling fan. This system operates in continuous wave (CW) mode and consists of a controller assembly, computer circuitry, interconnect wiring, and a handpiece. Optimal laser parameters, such as wavelength and power, were selected based on earlier animal experiments. A device operating at a wavelength of 1.45μ and at 4.5W continuous power level (CW), with a 5-mm beam spot and a 55°C set temperature were constructed for this investigation. The laser output is controlled by a foot-switch.

The laser is coupled to a 1-mm diameter fiber. Spherical lenses are mounted in combination with the delivery fiber to expand and focus the laser beam to a 5-mm spot size at a working distance of 2.54±1.25 cm. A laparoscopic handpiece was designed and built to fit within a 5-mm trocar. Surgeon control of the laser beam position is accomplished by maneuvering the instrument in proximity to the target as well as by external compression and movement of the abdominal wall. An inlet port allows continuous dry carbon dioxide gas purging of the sensor and sensor fiber to prevent any moisture accumulation on the handpiece. The mesh-solder coupon is continuously exposed to the laser while the laser beam is expanded and moved slowly over the entire solder surface area to expose and completely melt the solder.

Delivery of the mesh and mesh-solder constructs into the abdominal cavity was accomplished using a specially designed solder delivery tool. The tool is designed to fit within a 12-mm trocar. The solder-mesh construct is wound onto the shaft of the instrument before it is inserted into the trocar. A retention slot is provided to facilitate this process. The material is unwound from the tool once it has been inserted into the abdomen. The tool facilitates the precise positioning of the material at the surgical site and is sufficiently long to allow its use as a means of adjusting and maintaining the positioning of the material for initial fixation at the desired location.

In-Vivo Model

All animal studies were conducted in accordance with PHS guidelines and under a protocol approved by the Institutional Animal Care and Use Committee of Rochester General Hospital. Laparoscopy was accomplished using three 12-mm trocars in 2 female Yorkshire pigs weighing 20 kg to 25 kg. Anesthesia induction was carried out by using the mixture of 22-mg/kg ketamine and 1.1-mg/kg acetylpromazine intramuscularly and was maintained by 0.5% to 1.0% Fluothane inhalation. Laparoscopy was conducted with CO_2 insufflation at 12mm Hg. Each animal received simulated hernia closures using the study configurations according to random position assignment. Pa-

rietex TEC and Vicryl mesh (5 cm x 5 cm) segments were embedded in 55% collagen solder. The segments were inserted using the specially designed mesh introducer instrument. The solder-embedded Parietex TEC segments (Mesh/TAPP) were placed into the preperitoneal space after creating incisions in the peritoneum and creating an appropriately sized pocket with blunt dissection. Mesh/solder segments were fixed to the muscle surface using the CEE laser (1.45 μ, 4.5W CW, 5-mm spot, and 55C^{o} set temperature) with the custom laparoscopic handpiece designed for this purpose **(Figure 1)**. Closure of the peritoneum was accomplished by soldering the solder-embedded Vicryl mesh to the peritoneum **(Figure 2)** after bringing the incised peritoneal edges into proximity with each other (Mesh/TAPP). Nonembedded Parietex TEC mesh segments were inserted into the preperitoneal space and affixed to the muscle surface with Tisseel **(Figure 3)** applied to the area via a cannula that had been placed through a suction irrigation probe (Control). The peritoneal incision was closed using the Endo-hernia stapler (Control) to approximate the peritoneal wound edges **(Figure 4)**. The trocar sites were closed with 0-polydioxanone sutures in the fascia, and skin incisions were closed with 0-polypropylene sutures. Each animal received ceftriaxone 50 mg/kg and banamine 1 mg/kg IM at the conclusion of the procedure.

The animals were recovered and underwent second-look laparoscopy 6 weeks after surgery. The weld sites were assessed for integrity, adherence of the mesh, gross evidence of inflammation or tissue damage, and for the presence and severity of intraabdominal adhesions **(Figure 5)**. The mesh sites were harvested after the animals had been euthanized by intravenous pentobarbital (100 mg/kg) and potassium overdose while under general anesthesia. The abdominal wall tissues were excised and fixed in 10% formalin. Representative samples were taken, embedded in paraffin, and stained using Hematoxylin and Eosin (H & E), and Masson's trichrome stain (Trichrome) staining techniques. Stained sections were evaluated by light microscopy.

Figure 1. Intraoperative mesh fixation of solder-embedded Parietex TEC to the preperitoneal space with laser soldering with the specially designed CEE Laser handpiece.

Figure 2. An intraoperative view of closure of the peritoneal incision with laser soldering of solder-embedded Vicryl mesh to the peritoneal surface after the incision edges are brought into apposition.

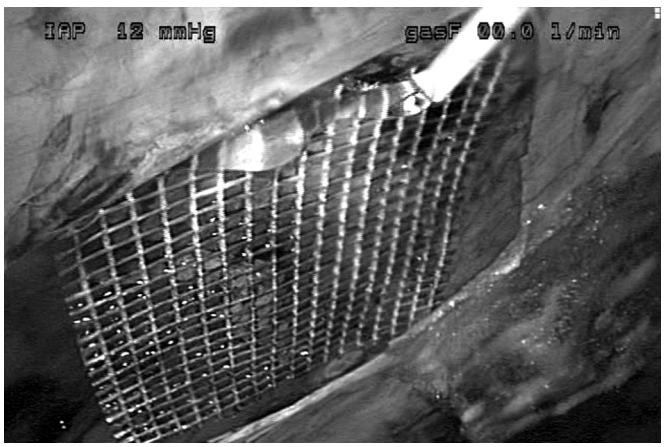

Figure 3. An intraoperative view of Parietex TEC mesh fixation in the preperitoneal space using Tisseel. The Tisseel is applied to the mesh surface using a catheter inserted into a suction irrigation cannula. Liquid material is placed in a top-down approach. The Tisseel material tended to drip, particularly when an attempt was made to affix mesh that was in a vertical or near vertical position.

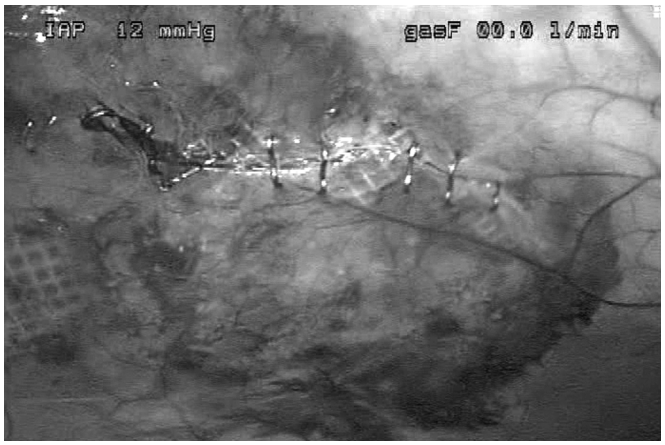

Figure 4. An intraoperative view of the Endo-Hernia staple closure of the peritoneal incision. Note that the staples tend to cut through the thin peritoneum.

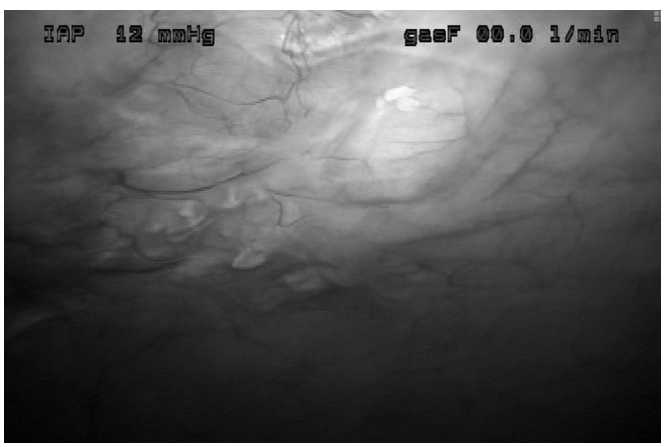

Figure 5. Second-look laparoscopy at 6 weeks postoperatively demonstrates complete peritoneal healing without evidence of scarring or adhesion formation at the laser solder of the transabdominal preperitoneal herniorrhaphy site. The Parietex TEC mesh is visible beneath the peritoneal surface.

RESULTS

The mesh-solder constructs were easily inserted and affixed to the musculature in the preperitoneal space in all cases. Solder fluidity and subsequent adherence was acceptable in both mesh to muscle and mesh to peritoneal surface fixation paradigms. Tisseel was initially quite fluid after mixing, and the material was prone to dripping and running, particularly when the herniorrhaphy location was more vertical or located on the ventral (anterior) surface of the abdominal wall **(Figure 3)**. The material clogged the cannula as it coagulated, necessitating forceful flushing of the cannula with saline both during and between uses. The edges of the peritoneal incisions could be brought into apposition in both the Mesh/TAPP and Control groups. However, the Endo-hernia staples occasionally cut through the relatively thin and friable porcine peritoneum, necessitating placement of additional staples to achieve closure of the peritoneal incision **(Figure 4)**. The Vicryl mesh-solder material was easily applied and soldered to the peritoneal surface **(Figure 2)**.

Second-look laparoscopy and harvest was performed 6 weeks after implantation. The subjects were healthy. The Parietex TEC mesh was incorporated, and there was no residual Vicryl or solder at the Mesh/TAPP sites. The peritoneal surface appeared smooth, with no evidence of scarring or adhesions **(Figure 5)**. The Parietex TEC remained in-situ in the preperitoneal space in all cases in both Mesh/TAPP and Control groups. Tissue histologies were similar in both groups and consistent with results from our prior studies.

DISCUSSION

The current pilot study evaluated the feasibility of using high-concentration, derivatized collagen to facilitate mesh fixation to the abdominal wall musculature and to provide secure closure of the peritoneum during transabdominal preperitoneal herniorrhaphy.

Vicryl (polyglactin) mesh was used as a structural lattice for peritoneal closure because the material handles easily, bonds readily with the collagen solder, and because tissue in-growth and permanence of the material are not required. The Vicryl mesh and collagen solder composite has favorable attributes in that it provides a strong, hydrophilic, easily applied, bioabsorbable material. The collagen-mesh composite affords secure coverage and closure of the peritoneum while maintaining structural integrity for a sufficient length of time to permit healing to occur. Other potential uses of this paradigm might include peritoneal coverage after ablation of endometriosis, anastomosis, and anastomotic reinforcement of gastrointestinal, vascular, or other structures and abdominal wall stabilization in contaminated wounds or polytrauma.

Tisseel is a fibrin sealant product that is composed of 2 components that are mixed in a common chamber prior to exiting the delivery cannula for use. This material was chosen as the source of the "fibrin glue" for mesh fixation in the Control group. Both fibrin glue and other tissue adhesives including cyanoacrylate compounds have been used for this purpose in an effort to avoid the use of staples and other permanent fixation devices.[8–10] The liq-

uid material tended to drip from the intended site of application, particularly when the mesh was located in a ventral or vertical position. The applicator clogged frequently during use. Closure of the peritoneal incision using liquid fibrin was not attempted in this pilot experiment. However, Vicryl mesh could potentially be fastened to the peritoneal surface using Tisseel.

Major factors that contribute to hernia recurrence following the use of prosthetic mesh techniques include insufficient mesh size or inadequate coverage of multiple hernia defects, inadequate mesh fixation, hematoma and seroma formation, folding or twisting of the material, and shear forces leading to dislodgement of the material.[3,4] Collagen tissue soldering has the potential to prevent or minimize these problems by improving the ability to apply and uniformly fix the prosthetic to the abdominal wall or the peritoneal surface. The use of sutures, staples, tacks, and other permanent methods for mesh fixation will be reduced or possibly eliminated. The ability to close the peritoneal surface with a hydrophilic absorbable material is likely to facilitate TAPP repair strategies and will reduce potential complications, such as intraabdominal adhesions and the potential for internal hernia secondary to disruption of the peritoneal closure.[19,21–28] The results reported herein demonstrate that an appropriate model for TAPP herniorrhaphy can be created and that the prototype materials and technologies described can be used effectively in vivo based on the minimum number of subjects necessary for an initial test of a hypothesis. Clearly, a larger study will be needed to refine the technique and to provide sufficient data for demonstration of statistical significance. This pilot study demonstrates that laser-assisted tissue soldering is feasible and provides an acceptable means of mesh fixation and peritoneal closure during TAPP hernia repair. Further development of this technique and these novel technologies is warranted.

CONCLUSION

This study investigated the feasibility of using derivatized collagen solder for mesh fixation and peritoneal closure for laparoscopic transabdominal preperitoneal herniorrhaphy (TAPP). The results of this pilot experiment demonstrate that laser-assisted soldering facilitates mesh fixation, achieves secure closure of the peritoneum, and enables healing without intraabdominal adhesion formation at the site of peritoneal closure. Further study of this paradigm is warranted.

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